



NDA 10-909/S-013

Schering Corporation  
Attention: Ms. Mary Jane Nehring  
Senior Director, Marketed Products  
2000 Galloping Hill Road  
Kenilworth, New Jersey

Dear Ms. Nehring:

Please refer to your supplemental new drug application dated October 5, 2001, received October 9, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Miradon (anisindione) Tablets

This "Changes Being Effected" supplemental new drug application provides for the following: a revision to the storage statement in the labeling from "Store between 15° and 25°C (59°-77°F)" to "Store at Controlled Room Temperature 20° -25° C (68°-77° F) [See USP]".

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted October 5, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Karen Oliver, Regulatory Project Manager, at (301) 827-7457.

Sincerely,

*{See appended electronic signature page}*

Liang Zhou, Ph.D.  
Chemistry Team Leader for the  
Division of Gastrointestinal and Coagulation Drug  
Products, (HFD-180)  
DNDC II, Office of New Drug Chemistry  
Center for Drug Evaluation and Research

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/s/

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Liang Zhou  
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